

REMARKS

The present application has been reviewed in light of the Final Office Action mailed July 11, 2008. In view of the Final Office Action, Applicant files herewith a Request for Continued Examination. By the present amendment, claims 1 and 2 have been amended as to spelling and to further clarify the claimed subject matter.

Claim Rejections under 35 USC § 103(a)

Claims 1-8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0028502 to Cummins (hereinafter "Cummins") in view of U.S. Patent No. 5,282,829 issued to Hermes (hereinafter "Hermes"). Applicant respectfully traverses the Examiner's rejection for at least the reasons stated herein.

As an initial matter, Applicant fails to appreciate the purpose for combining the staple of Cummins with the Hermes disclosure, since Hermes alone contemplates a surgical staple (Hermes col. 7 ll. 11-27). Staples, and the manner in which they commonly function, i.e., they fasten objects by being bent into shape, are well-known even to a layperson. Deformability is an inherent property of a staple. Therefore, relying on Hermes, in combination with Cummins merely for its teaching of a deformable staple, discloses no more than does Hermes alone.

There is no rational basis for a finding of obviousness

The Examiner takes the position that it would have been obvious to the skilled practitioner to modify the staple of Cummins to have at least one rupturable capillary, because allegedly Hermes at col. 5 ll. 2-12 states "such a modification provides focal

application of a medicine for the purpose of treating a specific region of tissue, while also providing a drug delivery system to a wound for the purpose of speeding up the healing process.”

The Examiner must provide “some articulated reasoning with some rationale underpinning to support the legal conclusion of obviousness.” *KSR Int'l. Co. v. Teleflex, Inc.*, et al., 550 U.S. __, 127 S.Ct. 1727, 82 USPQ2d 1385 (2007), (No. 04-1350), at p. 14. The Examiner must make “explicit” the rationale of “the apparent reason to combine the known elements in the fashion claimed,” including a detailed explanation of “the effects of demands known to the design community or present in the marketplace” and “the background knowledge possessed by a person having ordinary skill in the art.” *Id.* Further, the Examiner must “identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does”. *Id.*, at p. 15. Applicant maintains the Examiner has failed to articulate an explicit, rational reason why a person of ordinary skill in the art would combine Hermes and Cummins in the manner the Examiner suggests.

Applicant’s reading of Hermes reveals that nowhere within the cited passages, i.e., Hermes col. 5 ll. 2-12, nor in any other passages, does Hermes disclose a rupturable capillary. At most, Hermes discloses a “hollow core which may contain a drug, enzyme, peptide or diagnostic agent such as a releasable dye which may have no biological activity per se” (col.4 ll. 67-68 – col. 5 ll. 1-2). Indeed, Hermes teaches that the medicinal diffuses out of the device at a controlled rate into surrounding environment (col. 5 ll. 14-15), or that the medicinal may penetrate the wall of the device and diffuse into the surrounding environment at a rate governed by the number of pores and/or the

concentration of the medicinal (col. 5 ll. 19-34). In fact, each and every embodiment disclosed in Hermes evinces a controlled, gradual release of a medicinal compound, not a capillary being rupturable upon deformation...to dispense said liquid simultaneously with being ruptured, as recited in Applicant's claims.

Even assuming, arguendo, that one would combine the teachings of Hermes and Cummins, the resulting device would not work as intended. The Hermes device stores the medicinal within an interiorly disposed hollow core or cored region (col. 4, ll.12-13 and ll. 61-63). If, as the Examiner suggests, the interior porous core of a Hermes/Cummins device were to rupture to release the medicinal stored therein, the structural integrity of the porous staple would be irreversibly compromised. That is, in order to release the fluid, the walls of the staple itself would have to rupture which would necessarily weaken the staple, or even cause it to fragment, rendering the staple useless as a fastener.

Contrast Applicant's invention, which teaches at least one rupturable capillary disposed on [a] base leg of a surgical staple. Applicant's capillary ruptures when the staple is formed. Applicant's staple does not rupture. In this manner, Applicant discloses a novel and non-obvious surgical fastener that includes a capillary that is rupturable and able to deliver fluids while maintaining full, uncompromised structural integrity of the staple.

Applicant respectfully submits that the Examiner has failed to articulate an explicit, rational reason why a person of ordinary skill in the art would combine the controlled release of Hermes with the Cummins staple to practice Applicant's rupturable capillary. This is particularly true since Hermes teaches the exact opposite result taught

by Applicant: a controlled release versus the burst of a rupture. Moreover, even if one could combine the Hermes staple with the Cummins staple, the resulting combination would not work as intended for at least the reasons stated hereinabove. Therefore, for at least these reasons, Applicant respectfully requests the rejection under 35 USC § 103(a) be withdrawn.

Nonobviousness is indicated where the references teach away

"[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious."

KSR, at p. 12, citing *United States v. Adams*, 383 U. S. 39, 40 (1966), at 51-52.

Applicant maintains that Hermes does not teach a rupturable capillary, but rather, teaches away from Applicant's disclosure because in every instance, Hermes teaches a slow and methodic leaking, diffusion or release of the medicinal into the target area. The fastener disclosed by Hermes is designed not to rupture (col. 4, ll. 23-44). Hermes relies on such mechanisms as chemical reactions, rates of diffusion, chemical concentrations, and the size of pores to govern the rate at which the medicinal is delivered into the target tissue through the implant in a controlled manner. In contrast, Applicant's claims 1 and 2 as amended recite dispensing of the fluid simultaneously upon deformation of a surgical fastener which by definition is an immediate event that involves the rapid, physical buckling or bending of the fastener into a desired configuration against the skin tissue while at the same expelling the fluid from the capillary.

As can be appreciated, the deliberate, controlled release of medicant of Hermes (col. 5, ll. 42-45) unquestionably teaches away from Applicant's teachings of

mechanically exploding fluid from a capillary simultaneously upon deformation of a fastener. For at least this reason, and particularly in view of the instructions of *KSR*, Applicant respectfully requests the rejection under 35 USC § 103(a) be withdrawn.

Claim terms must be given their plain meaning

The Examiner has interpreted the term "rupturable" to encompass a point at which "a surface of a capillary dissolves."

The words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004); *see also* MPEP § 2111.01. "Although the PTO must give claims their broadest reasonable interpretation, this interpretation must be consistent with the one that those skilled in the art would reach." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359 (Fed. Cir. 2004), citing *In re Cortright*, 165 F.3d 1353, 1358 (Fed.Cir.1999).

Here, the Examiner's interpretation of the word "rupture" to include the "dissolving" (i.e. the melting, liquefying, gradually fading or disappearing) of a capillary surface is inconsistent with the plain meaning of the word "rupture" (i.e., bursting, exploding). Moreover, Applicant respectfully submits that one skilled in the art would not interpret the term "rupture" to encompass dissolving.

The Examiner further takes the position that Hermes reasonably suggests the "simultaneous release of plural capillaries in the surgical staples, wherein the capillaries do not rupture to permit the simultaneous release until the surgical staples have been

positioned within tissue." In response, Applicant has amended claim 2 to further clarify that at least one capillary is rupturable to dispense said liquid simultaneously with the deformation of each surgical fastener.

CONCLUSION

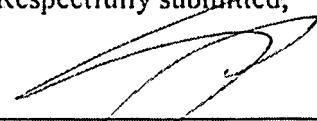
In light of the foregoing, Applicant respectfully submits that independent claims 1-2 and dependent claims 3-8 as currently amended are patentably distinguishable over the cited references and the other references of record. Accordingly, early and favorable consideration of this application is earnestly requested.

Should the Examiner believe that a telephone or personal interview may facilitate resolution of any remaining matters, she is respectfully requested to contact Applicant's attorney at the number indicated below.

Please charge any deficiency as well as any other fee(s) that may become due under 37 C.F.R. § 1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s), to Deposit Account No. 21-0550.

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Respectfully submitted,


Edward C. Meagher
Reg. No. 41,189
Attorney for Applicants

Carter, DeLuca, Farrell & Schmidt, LLP
445 Broad Hollow Road, Suite 225
Melville, New York 11747
Tel.: (631) 501-5700
Fax: (631) 501-3526

Correspondence address:
COVIDIEN
60 Middletown Avenue
North Haven, CT 06473
203-492-2000